K121201

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05 Summary of 510(k) Submission

Submitter Information:

Address:	St. Shine Optical Co., Ltd. 4,5F No. 276-2, Sec. 1, Ta Tung Rd. Hsi Chih Dist., 221, New Taipei City Taiwan R.O.C.
Registration No.:	9617499
Contact Person:	Thomas Kuo, Manager, R&D Div.
Telephone:	886-2-2647-9356
Fax:	886-2-8691-6776
Date Prepared:	11. Oct., 2012

Device:

Common Name:	Soft (Hydrophilic) Contact Lens
Trade/Proprietary Name:	Saview-Aqua 55 UV (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens Saview-Aqua 55 UV Toric (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens Saview-Aqua 55 UV Multifocal (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens
Classification Name:	Soft (Hydrophilic) Contact Lens (daily wear)
Device Classification:	Class II (21 CFR 886.5925)
Product Code:	LPL
Panel:	Ophthalmic

Predicate Devices:

The predicate devices are Safi-gel Daily Disposable (methafilcon A) Soft (hydrophilic) Lens, Safi-gel Daily Disposable Toric (methafilcon A) Soft (hydrophilic) Lens, and Safi-gel Daily Disposable Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens covered under 510(k) K090806 and 55 UV (methafilcon A) Soft (hydrophilic) Contact Lens, 55 UV Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens and 55 UV Toric (methafilcon A) Soft (hydrophilic) Contact Lens covered under 510(k) K051095.

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Description of Devices:

The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate and methacrylic acid crosslinked with ethylene glycol dimethacrylate, and using azobisisobutyronitrile (AIBN) as the initiator. A UV absorbing monomer, 2-[3-(2H-Benzotriazol-2yl)-4-hydroxyphenyl] ethyl methacrylate, is incorporated into the lens polymer and used to block UV radiation. The UV blocker for Saview-Aqua 55 UV (methafilcon A) Visibility tinted Soft (Hydrophilic) Contact Lens averages 87.630 % in the UVA range of 316 nm to 380 nm and 98.975 % in the UVB range of 315 nm to 280 nm. The lens contains 55% water by weight and each lens is supplied sterile in a blister container containing 0.2 % hyaluronic acid polymer in saline solution. The lens is visibility tinted using Pigment Blue 15(Copper phthalocyanine) to make the lens more visible for handling.

The Saview-Aqua 55 UV (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is available as a single vision lens.

The Saview-Aqua 55 UV Toric (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is available in a double slab-off back surface design. The lens design incorporates a cylinder and base curve. From the bi-curve reduced optic front surface, there exists a slab-off of the upper and lower half of the lens. This makes both sides thicker at the horizontal level on the front surface to keep the axis stable.

The Saview-Aqua 55 UV Multifocal (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is available as an aspherical multifocal lens.

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Table 1 Comparison Chart

Device	**Saview-Aqua 55 UV, Saview-Aqua 55 UV Toric, and Saview-Aqua 55 UV Multifocal Soft (Hydrophilic) Contact Lens**	**55 UV, 55UV Multifocal, and 55 UV Toric Soft (Hydrophilic) Contact Lens** - K051095	**Safi-gel, Safi-gel Toric and Safi-gel Multifocal Soft (Hydrophilic) Contact Lens** - K090806
Material (Classification)	methafilcon A (Group 4)	methafilcon A (Group 4)	methafilcon A (Group 4)
Indication for use	myopia, hyperopia, presbyopia and astigmatism	myopia, hyperopia, presbyopia and astigmatism	myopia, hyperopia, presbyopia and astigmatism
Water content	55 %	55 %	55 %
Visible light transmittance (381 nm ~ 780 nm)	96.78 %	90.3%	90.30 %
UV Transmittance **UVA**(316 nm ~ 380 nm) **UVB**(280 nm ~ 315 nm)	6.7% 12.370 % 1.025 %	9.1 % 15.816 % 2.435 %	9.3 %
Dk (35° C)	21.4×10^{-11}	18.9×10^{-11}	18.9×10^{-11}
Powers	+12.00D to -20.00D; Cylinder powers -0.50D to -2.50D (Saview-Aqua 55 UV Toric only); Continuous add power to +3.25 (Saview-Aqua 55 Multifocal only)	+4.00 D to -20.00 D; Cylinder powers 0.50 D to -2.50 D (55 UV Toric only); Continuous add power to +3.25 (55UV Multifocal only)	+4.00D to -20.00D; Cylinder powers -0.50D to -2.50D (Safi-gel Toric only); +12.00 D to -20.00 D Continuous add power to +3.25 (Safi-gel Multifocal only)
Color	Pigment blue 15	Pigment blue 15	Pigment blue 15
Refractive index	1.404 (wet)	1.410 (wet)	1.410 (wet)
Method of manufacture	Moulded	Moulded	Moulded
Package Storage saline solution	Saline solution containing hyaluronic acid polymer	Saline solution	Saline solution with hyaluropolymer

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Indication for Use:

The Saview-Aqua 55 UV (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The Saview-Aqua 55 UV Toric (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive astigmatism up to 2.50 diopters that does not interfere with visual acuity.

The Saview-Aqua 55 UV Multifocal (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity and require add power of up to +3.25 diopters.

The Saview-Aqua 55 UV, Saview-Aqua 55 UV Toric and Saview-Aqua 55 UV Multifocal lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The Saview-Aqua 55 UV, Saview-Aqua 55 UV Toric and Saview-Aqua 55 UV Multifocal lenses are to be prescribed for single-use daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

Description of Safety and Substantial Equivalence:

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the Saview-Aqua 55 UV, Saview-Aqua 55 UV Toric, and Saview-Aqua 55 UV Multifocal (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens, and to establish substantial equivalence to the predicate devices.

Results of Acute Systemic Injection, Ocular Irritation and In Vitro Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. The Saview-Aqua 55 UV, Saview-Aqua 55 UV Toric, and Saview-Aqua 55 UV Multifocal (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens were extracted and evaluated for presence of residue. Results showed no evidence of unsafe amounts of residue in the

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extracts. Moreover, results of Oral Toxicity, Acute Ocular Irritation and In Vitro Cytotoxicity Tests show the packaging or the storage solution to be non-toxic and non-irritating as well. Physicochemical testing of the Saview-Aqua 55 UV Lenses demonstrated equivalency to the predicate devices.

Conclusion:

Information submitted in the 510(k) establishes that the Saview-Aqua 55 UV, Saview-Aqua 55 UV Toric, and Saview-Aqua 55 UV Multifocal (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown our products remain sterile and the properties do not change before the expiration date. Therefore, the devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 26 2012

St. Shine Optical Co., Ltd.
Mr. Thomas Kuo
Manager, R&D Division
4,5F No. 276-2, Sec. 1, Ta Tung Rd.
Hsi Chih Dist., 221 New Taipei City
Taiwan R.O.C.

Re: K121201
Trade/Device Name: Saview-Aqua 55 UV (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens, Saview-Aqua 55 UV Toric (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens, Saview-Aqua 55 UV Multifocal (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Codes: LPL, MVN
Dated: September 24, 2012
Received: October 1, 2012

Dear Mr. Kuo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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04 Indications for Use Statement

510(k) Number (if known): K121201

Device Name:

Saview-Aqua 55 UV (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens, Saview-Aqua 55 UV Toric (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens, Saview-Aqua 55 UV Multifocal (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens

Indications for Use:

The Saview-Aqua 55 UV (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity.

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The Saview-Aqua 55 UV Multifocal (methafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity and require add power of up to +3.25 diopters.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marc Robboy

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K121201